Available online at www.sciencedirect.com
ScienceDirect
European Journal of Obstetrics & Gynecology and Reproductive Biology 138 (2008) 222–225
ejog European Journal of Obstetrics & Gynecology and Reproductive Biology
www.elsevier.com/locate/ejogrb

Long-term outcome of hysteroscopic endometrial ablation without endometrial preparation

Maurizio Rosati [a], Alessandro Vigone [b,*], Francesco Capobianco [a], Daniela Surico [b], Elena Amoruso [b], Nicola Surico [b]

[a] *Department of Obstetrics and Gynecology, San Camillo Hospital, Trento, Italy*
[b] *Department of Obstetrics and Gynecology, Amedeo Avogadro University of Eastern Piedmont, Novara, Italy*

Received 26 November 2005; received in revised form 20 July 2007; accepted 14 August 2007

Abstract

Objective: To describe the three-step hysteroscopic endometrial ablation (EA) technique without endometrial preparation, and its long-term outcomes.
Study design: Four hundred and thirty-eight premenopausal women with menorrhagia or menometrorrhagia underwent three-step hysteroscopic EA, which consists of rollerball ablation of the fundus and cornual regions, a cutting loop endomyometrial resection of the rest of the cavity, and rollerball redessication of the whole pre-ablated uterine cavity. The main outcome measures were menstrual status, level of satisfaction with the procedure, and the need for repeat ablation or hysterectomy. Questionnaires were completed for 385 women (87.9%) with a mean follow-up of 48.2 months.
Results: One hundred and eighty-four responders (47.8%) reported amenorrhea; 177 (46%) had light to normal flow. One patient (0.3%) underwent repeat ablation and 20 (5.2%) underwent hysterectomy: 15 (3.9%) because of endometrial ablation failure and 5 (1.3%) because of indications unrelated to the ablation (three cases of atypical endometrial hyperplasia and two cases of fibroids). Two hundred and ninety-two patients (75.8%) were very satisfied, and 78 (20.3%) satisfied with the results. No major complications occurred and three women (0.8%) became pregnant during the follow-up period.
Conclusions: EA is safe and effective means of treating of menorrhagia and menometrorrhagia in premenopausal women, and helps avoid hysterectomy in 95% of patients suffering from heavy bleeding, with or without uterine fibroids. Women should be informed that the procedure is not contraceptive and that pregnancy is possible after treatment.

Keywords: Endometrial ablation; Menorrhagia; Outcome; Pregnancy

1. Introduction

Menorrhagia is a significant cause of premenopausal morbidity, accounting for 12% of referrals to gynecologists [1]. Endometrial ablation is a well-established means of treating heavy menstrual bleeding that has a number of advantages over hysterectomy: the avoidance of major surgery, a short operative time, a short hospital stay, and a rapid return to normal activities [2–4]. Most published data indicate that it is effective in 80–90% of cases, and have a low complication rate [5–7].

The aim of this study was to describe the surgical details of the three-step hysteroscopic endometrial ablation (EA) technique without endometrial preparation, and the long-term outcomes of the procedure.

2. Materials and methods

Between March 1997 and September 2003, 438 consecutive premenopausal women underwent EA for the

* Corresponding author at: Department of Obstetrics and Gynecology, Ospedale Maggiore della Carità, Corso Mazzini 18, 28100 Novara, Italy. Tel.: +39 0321 3733780; fax: +39 0321 3733659.
E-mail address: alevigo@katamail.com (A. Vigone).

0301-2115/$ – see front matter
doi:10.1016/j.ejogrb.2007.08.013

first time at San Camillo Hospital, Trento, Italy: 178 (46.2%) were treated because of menorrhagia and 260 (53.8%) because of menometrorrhagia. All of them were evaluated preoperatively by means of a physical examination, cervical smear, transvaginal pelvic ultrasonography, diagnostic office hysteroscopy, and a Novak cannula endometrial biopsy. The exclusion criteria were significant uterovaginal prolapse, a uterus larger than at 12 weeks' gestation, uterine malignancy or its precursors, a desire for future pregnancy, and endometriosis or inflammatory pelvic disease. No pharmacological or surgical pre-thinning of the endometrium was used; cefazolin 2 g was administered intravenously before surgery.

The interventions were carried out under spinal or general anesthesia using a 26F dual-channel irrigating resectoscope (Karl Storz, Tuttlingen, Germany), a rollerball and a loop electrode. A 1.5% glycine solution in 3 L bags was used for uterine distension and irrigation, electronically controlled by Hamou Endomat (Karl Storz). Fluid balance was very carefully monitored throughout the procedure in order to avoid fluid overload. After placing a Graves speculum in the vagina, the cervix was grasped with Pozzi forceps and dilated to Hegar No. 10.

The procedure used in all cases was three-step hysteroscopic EA, which consists of (1) ablation of the fundus and cornual regions using a 3-mm rollerball set at 130 W, pure cut; (2) endomyometrial resection of the rest of the cavity using a 24F cutting loop set at 130 W, pure cut, sparing the isthmic mucosa; and (3) rollerball redessication of the whole pre-ablated uterine cavity with 130 W cutting current. Submucosal fibroids or polyps were resected using the cutting loop before the second step of the procedure. All of the patients received a single intravenous bolus of antibiotic. Endometrial strips, and the removed fibroids and polyps were sent for histological evaluation.

The patients were followed up by means of telephone enquiries and retrospective analyses of their medical charts. The main outcome variables were current menstrual status, level of satisfaction with the procedure (evaluated using a five-point ordinal scale ranging from 1 = very dissatisfied to 5 = very satisfied), and the need for repeat ablation or hysterectomy.

The data were analysed by means of the χ^2 test and Fisher's exact test using Stata 8 statistical software; a p value of ≤ 0.05 was considered statistically significant.

The study was approved by our local Ethics Committee, and all of the patients gave their informed consent before the operation.

3. Results

Long-term outcome questionnaires were completed for 385 women (87.9%) with a mean (±S.D.) follow-up of 48.2 ± 24.2 months (range 9–86). Their mean age at treatment was 46.4 ± 4.7 years (range 33–56), median parity 2 (range 0–6), and mean BMI 23.6 ± 4 (range 16–40). The median duration of symptoms was 12 months (range 1–134). One hundred and nineteen patients (30.9%) had previously undergone conservative surgery, such as dilatation and curettage or operative hysteroscopy; none had undergone previous endometrial ablation. Preoperative ultrasonography revealed that 143 patients (37.1%) had uterine fibroids; 19 women (4.9%) had undergone previous tubal ligation.

The procedure was performed under spinal anesthesia in 322 patients (83.6%) and under general anesthesia in 63 (16.4%), and was successful in all cases. The mean operating time was 33.9 ± 12 min (range 8–90) and the mean fluid deficit was 96.1 ± 241.2 ml (range 0–1500). Uterine fibroids were resected in 49 cases (12.7%) and polyps in 119 (30.9%). Three hundred and sixty-seven patients (95.3%) were discharged home within 24 h of the end of the procedure.

No major complications occurred. The minor short-term complications were two cases (0.5%) of cervical laceration during dilatation recognised intraoperatively; eight cases (2.1%) of hemorrhage, one of which required the application of a Foley balloon catheter; and two cases (0.5%) of excessive fluid absorption (>1500 ml) treated by diuretics and catheterisation. Five patients (1.3%) reported nausea and vomiting, 1 (0.3%) urinary retention, 13 (3.4%) headache, and 2 (0.5%) with pyrexia. The long-term complications included two cases (0.5%) of hematometra and five (1.3%) of pelvic pain. Three patients (0.8%) subsequently became pregnant: one reached term without complications, one experienced an early miscarriage, and one underwent voluntary abortion for psychosocial reasons.

Histology revealed a normal endometrium in 363 cases (94.3%), endometrial hyperplasia without atypia in 18 (4.7%), and atypical endometrial hyperplasia in 3 (0.8%). Uterine fibroids were histopathologically diagnosed in 40 cases (10.4%) and adenomyosis in 14 (3.6%).

There were no statistically significant differences in general and surgical characteristics between the responders and non-responders.

Table 1 shows the menstrual pattern of the women at the time of post-procedural assessment: 184 (47.8%) reported amenorrhea and 177 (46%) reported light to normal flow.

Table 1
Menstrual pattern after EA

	No.	Percentage
Amenorrhea	184[a]	47.8
Hypomenorrhea	150	38.9
Eumenorrhea	27	7
Metrorrhagia	1	0.3
Menorrhagia	2	0.5
Menometrorrhagia	0	0
Spotting	1	0.3
Hysterectomy	20[b]	5.2

[a] 63 developed menopausal symptoms during follow-up.
[b] 11 complained of menometrorrhagia, and one experienced spotting.

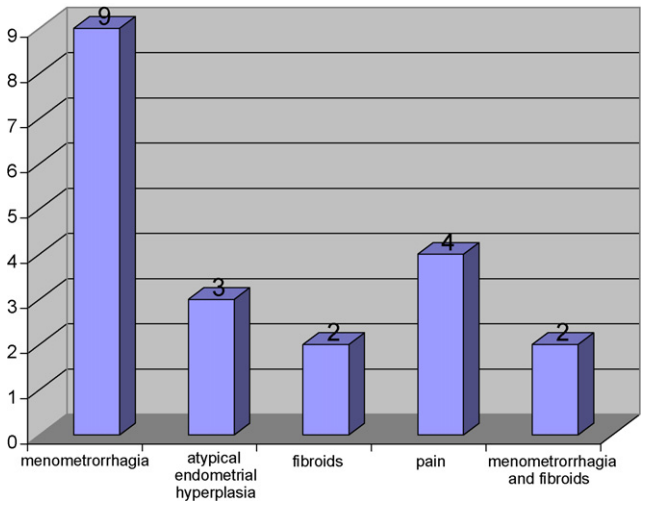

Fig. 1. Indications for hysterectomy (no. of patients).

Only 21 patients required a further intervention: 1 (0.3%) underwent repeat endometrial ablation and 20 (5.2%) underwent hysterectomy. The indications for hysterectomy are shown in Fig. 1: as five patients had indications unrelated to EA (three cases of atypical endometrial hyperplasia and two cases of uterine fibroids), the true rate of hysterectomy due to EA failure was 3.9%. The percentage failure by age at the time treatment (<44, 44–49 and >49) was, respectively, 5.8%, 5.5% and 5.2%; the differences were not statistically significant ($p = 0.96$). The failures were recorded within 24 months of the procedure in 13 cases, 24–48 months in 4 cases, and >48 months in 4 cases. The success rates in the two groups of women with long-term follow-up (24–48 and >48 months) were lower than that in the patients followed up for <24 months ($\chi^2 = 12.5$; $p < 0.01$).

The majority of the women were very satisfied with the outcome (Table 2). Three hundred and sixty-six of the respondents to the questionnaire (95.1%) said they would undergo the same treatment again, and 370 (96.1%) said they would recommend EA to their best friend.

The data regarding the time taken to return to normal activities show that 235 women (61%) were back to normal the day after the procedure, and 14 (3.6%) took more than eight days to recover.

Table 2
Level of satisfaction after EA

	No.	Percentage
Very satisfied	292	75.8
Satisfied	78	20.3
Neutral	5	1.3
Dissatisfied	2	0.5
Very dissatisfied	8	2.1

4. Discussion

Endometrial ablation has become a widely accepted alternative to hysterectomy for the treatment of menorrhagia since the first-generation laser [8], rollerball [9] and resection [10] techniques were introduced into gynecological practice in the 1980s. Although a number of studies have demonstrated that these procedures are effective and safe [6,7], second-generation techniques have been developed with the aim of making endometrial ablation easier, safer, quicker and possibly even more effective. These include the use of heated balloon systems [11], hot saline circulation [12], microwaves [13], monopolar/bipolar electrical devices [14], laser devices [15], and cryosurgery [16]. The results concerning the efficacy and safety of these newer methods are encouraging, but longer term data are required in order to establish their role and benefit in clinical practice [6,17].

Three-step hysteroscopic EA is a minimally invasive means of treating menorrhagia and menometrorrhagia that requires hysteroscopic skills and an experienced surgeon. In the first step, a rollerball is used to destroy the endometrium of the fundus and cornual regions as this technique is considered slightly safer than using a loop in terms of perforation of the thinnest parts of the myometrium [6].

Step 2 involves endomyometrial resection of the rest of the cavity by means of a loop and, in our series, provided histological specimens that revealed atypical endometrial hyperplasia in three cases although their preoperative endometrial biopsies were negative. These three women underwent hysterectomy in order to avoid the risk of progression to endometrial carcinoma. Stovall et al. have reported that pathological results at hysterectomy do not agree with histological findings at Novak cannula endometrial sampling in 4% of cases, a problem that could be eliminated by using visually directed endometrial biopsies [18]. It should be pointed out that laser, rollerball and second-generation endometrial ablation techniques do not provide adequate endometrial tissue for pathological assessment, thus leading to inappropriate under-treatment in the presence of pre-malignant and malignant endometrial diseases. The isthmic mucosa was spared to permit light menstrual flow and to prevent the risk of hematometra by maintaining transcervical drainage.

Step 3 is intended to 'radicalise' endometrial ablation by rollerball redessicating of the whole pre-ablated uterine cavity in order to destroy any residual pockets of endometrium left after steps 1 and 2. We believe that step 3 is the key to the efficacy of the procedure because 'radical' endometrial ablation provides lasting symptom relief and substantially reduces the risk of hematometra, post-ablation sterilisation syndrome, and endometrial cancer.

The hysterectomy rate in our series was very low: only 3.9% of the patients were hysterectomised during the follow-up period due to EA failure.

It has previously been shown that the success rate of EA declines with the length of follow-up [19,20], and that there is an inverse correlation with patients' age [20,21]. The former was confirmed by our findings but, like Amso et al.

[22] we did not find any impact of age on outcome. However, we did not look for any correlation between age, success rate and menopausal status.

The majority of our patients were very satisfied with the results, and no major complications occurred.

Three pregnancies (0.8%) were reported during the follow-up period, which is in line with other published findings (0.2–1.6% of pregnancies following endometrial ablation) [23,24]. Given the low rate of hematometra and post-ablation sterilisation syndrome in our patients, one possible explanation is that the pregnancies were related to regenerated endometrium from the spared isthmus rather than to incomplete endometrial destruction.

Consideration should also be given to preoperative endometrial preparation, which has been reported to be associated with shorter operative times, less fluid absorption and a better menstrual outcome [6,25]. We did not use any pharmacological or surgical pre-thinning of the endometrium (mainly because of the considerable side effects of hormonal preparations and the reduced hysteroscopic visualisation caused by curettage), but this did not seem to compromise the outcome of EA.

In conclusion, our results show that three-step hysteroscopic EA without endometrial preparation can lead to a very high success rate and provide evidence that the technique is effective and safe in the treatment of menorrhagia and menometrorrhagia in premenopausal women with or without uterine fibroids. Women should be informed that the procedure is not contraceptive and that pregnancy is possible after treatment.

Acknowledgement

The authors would like to thank Daniela Ferrante, Ph.D., for the statistical analysis.

References

[1] Coulter A, Noone A, Goldacre M. General practitioners' referrals to specialist outpatient clinics. I. Why general practitioners refer patients to specialist outpatient clinics. BMJ 1989;299:304–6.
[2] O'Connor H, Broadbent JA, Magos AL, McPherson K. Medical Research Council randomised trial of endometrial resection versus hysterectomy in management of menorrhagia. Lancet 1997;349:897–901.
[3] Aberdeen Endometrial Ablation Trials Group. A randomised trial of endometrial ablation versus hysterectomy for the treatment of dysfunctional uterine bleeding: outcome at four years. Br J Obstet Gynaecol 1999;106:360–6.
[4] Pinion SB, Parkin DE, Abramovich DR, et al. Randomised trial of hysterectomy, endometrial laser ablation, and transcervical endometrial resection for dysfunctional uterine bleeding. BMJ 1994;309:979–83.
[5] Nagele F, Rubinger T, Magos A. Why do women choose endometrial ablation rather than hysterectomy? Fertil Steril 1998;69:1063–6.
[6] Garry R. Evidence and techniques in endometrial ablation: consensus. Gynaecol Endosc 2002;11:1–57.
[7] Overton C, Hargreaves J, Maresh M. A national survey of the complications of endometrial destruction for menstrual disorders: the MISTLETOE study. Minimally invasive surgical techniques—laser, endothermal or endoresection. Br J Obstet Gynaecol 1997;104:1351–9.
[8] Goldrath MH, Fuller TA, Segal S. Laser photovaporization of endometrium for the treatment of menorrhagia. Am J Obstet Gynecol 1981;140:14–9.
[9] Townsend DE, Richart RM, Paskowitz RA, Woolfork RE. "Rollerball" coagulation of the endometrium. Ostet Gynecol 1990;76:310–4.
[10] Magos AL, Baumann R, Turnbull AC. Transcervical resection of endometrium in women with menorrhagia. BMJ 1989;298:1209–12.
[11] Neuwirth RS, Duran AA, Singer A, MacDonald R, Bolduc L. The endometrial ablator: a new instrument. Obstet Gynecol 1994;83:792–6.
[12] Corson SL. A multicenter evaluation of endometrial ablation by Hydro ThermAblator and rollerball for treatment of menorrhagia. J Am Assoc Gynecol Laparosc 2001;8:359–67.
[13] Sharp NC, Cronin N, Feldberg I, Evans M, Hodgson D, Ellis S. Microwaves for menorrhagia: a new fast technique for endometrial ablation. Lancet 1995;346:1003–4.
[14] Cooper J, Gimpelson R, Laberge P, et al. A randomized, multicenter trial of safety and efficacy of the NovaSure system in the treatment of menorrhagia. J Am Assoc Gynecol Laparosc 2002;9:418–28.
[15] Donnez J, Polet R, Mathieu PE, Konwitz E, Nisolle M, Casanas-Roux F. Endometrial laser interstitial hyperthermy: a potential modality for endometrial ablation. Obstet Gynecol 1996;87:459–64.
[16] Dobak JD, Ryba E, Kovalcheck S. A new closed-loop cryosurgical device for endometrial ablation. J Am Assoc Gynecol Laparosc 2000;7:245–9.
[17] Bongers MY, Mol BW, Brolmann HA. Current treatment of dysfunctional uterine bleeding. Maturitas 2004;47:159–74.
[18] Stovall TG, Ling FW, Morgan PL. A prospective, randomized comparison of the Pipelle endometrial sampling device with the Novak curette. Am J Obstet Gynecol 1991;165:1287–90.
[19] Martyn P, Allan B. Long-term follow-up of endometrial ablation. J Am Assoc Gynecol Laparosc 1998;5:115–8.
[20] Seidman DS, Bitman G, Mashiach S, Hart S, Goldenberg M. The effect of increasing age on the outcome of hysteroscopic endometrial resection for management of dysfunctional uterine bleeding. J Am Assoc Gynecol Laparosc 2000;7:115–9.
[21] Litta P, Merlin F, Pozzan C, et al. Transcervical endometrial resection in women with menorrhagia: long-term follow-up. Eur J Obstet Gynecol Reprod Biol 2006;1(125):99–102.
[22] Amso NN, Fernandez H, Vilos G, et al. Uterine endometrial thermal balloon therapy for the treatment of menorrhagia: long-term multicentre follow-up study. Hum Reprod 2003;18:1082–7.
[23] Pugh CP, Crane JM, Hogan TG. Successful intrauterine pregnancy after endometrial ablation. J Am Assoc Gynecol Laparosc 2000;7:391–4.
[24] El-Toukhy T, Hefni M. Pregnancy after hydrothermal endometrial ablation and laparoscopic sterilisation. Eur J Obstet Gynecol Reprod Biol 2003;106:222–4.
[25] Vercellini P, Perino A, Consonni R, Trespidi L, Parazzini F, Crosignani PG. Treatment with a gonadotrophin releasing hormone agonist before endometrial resection: a multicentre, randomised controlled trial. Br J Obstet Gynaecol 1996;103:562–8.